CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-04 Medicare Claims Processing	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 1723	**Date: May 1, 2009**
	Change Request 6455

Subject: Ensuring Only Clinical Trial Services Receive Fee-For-Service Payment on Claims Billed for Managed Care Beneficiaries

I. SUMMARY OF CHANGES: This Change Request (CR) is updating system editing to ensure accurate billing, and ultimately correct pricing of clinical trial services provided to managed care beneficiaries.

New / Revised Material
Effective Date: October 1, 2009
Implementation Date: October 5, 2009

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)
R=REVISED, N=NEW, D=DELETED-*Only One Per Row.*

R/N/D	Chapter / Section / Subsection / Title
R	32/Table of Contents
R	32/69.6/Requirements for Billing Routine Costs of Clinical Trials
R	32/69.9/Billing and Processing Fee for Service Claims for Covered Clinical Trial Services Furnished to Managed Care Enrollees

III. FUNDING:
SECTION A: For Fiscal Intermediaries and Carriers:
No additional funding will be provided by CMS; Contractor activities are to be carried out within their operating budgets.

SECTION B: For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

Business Requirements

Manual Instruction

**Unless otherwise specified, the effective date is the date of service.*

Attachment – Business Requirements

Pub. 100-04	Transmittal: 1723	Date: May 1, 2009	Change Request: 6455

SUBJECT: Ensuring Only Clinical Trial Services Receive Fee-For-Service Payment on Claims Billed for Managed Care Beneficiaries

Effective Date: October 1, 2009

Implementation Date: October 5, 2009

I. GENERAL INFORMATION

A. Background: The Centers for Medicare & Medicaid Services (CMS) has recognized a need to provide additional clarification in regards to billing and processing clinical trial services. This Change Request (CR) is updating system editing to ensure accurate billing, and ultimately correct pricing of clinical trial services provided to managed care beneficiaries.

B. Policy: For dates of service on or after September 19, 2000, and until notified otherwise by CMS, Medicare contractors will pay for covered clinical trial services furnished to beneficiaries enrolled in managed care plans. Medicare contractors should determine the payment for covered clinical trial services furnished to beneficiaries enrolled in managed care plans in accordance with applicable fee for service rules, except that beneficiaries are not responsible for the Part A or Part B deductibles (i.e., assume the Part A or Part B deductible has been met). Managed care enrollees are liable for the coinsurance amounts applicable to services paid under Medicare fee for service rules. The Medicare deductible applies to fee for service Medicare clinical trial claims.

II. BUSINESS REQUIREMENTS TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
6455.1	CWF shall create a new error code to reject outpatient clinical trial claims (claims with a condition code 30 and a secondary diagnosis code V707) for managed care enrollees (i.e., positive GHOD file exists in CWF) when there is at least one line on the claim that does not contain either a HCPCS modifier Q0 or Q1.									X	
6455.2	Based off of the CWF reject, FISS shall line item reject lines that do not contain either a HCPCS modifier Q0 or Q1. (Such lines are not considered related to the clinical trial and, therefore, are not payable under FFS for managed care enrollees.)						X				
6455.2.1	Contractors shall use the following messages when line-item rejecting:	X		X							

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
	Medicare Summary Notice: **11.1** - Our records show that you are enrolled in a Medicare health plan. Your provider must bill this service to the plan. **11.1** - Nuestros archivos muestran que usted está inscrito en un plan de salud Medicare. Su proveedor debe facturarle este servicio al plan." Claim Adjustment Reason Code: **24** - Charges are covered under a capitation agreement/managed care plan. Group Code: **CO** – Contractual Obligation										

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
6455.3	A provider education article related to this instruction will be available at http://www.cms.hhs.gov/MLNMattersArticles/ shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web site and include information about it in a listserv message within one week of the availability of the provider education article. In addition, the provider education article shall be included in your next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program	X		X							

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
	correctly.										

IV. SUPPORTING INFORMATION

Section A: For any recommendations and supporting information associated with listed requirements:
"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

Section B: For all other recommendations and supporting information:

V. CONTACTS

Pre-Implementation Contact(s):
Joe Bryson at 410-4786-2986 or joseph.bryson@cms.hhs.gov

Post-Implementation Contact(s): Regional Office

VI. FUNDING

Section A: For *Fiscal Intermediaries (FIs), Carriers and Regional Home Health Carriers (RHHIs)*:

No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

Section B: *For Medicare Administrative Contractors (MACs)*:

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

Medicare Claims Processing Manual

Chapter 32 – Billing Requirements for Special Services

Table of Contents

(Rev. 1723, 05-01-09)

69.6 - Requirements for Billing Routine Costs of Clinical Trials

(Rev.1723, Issued: 05-01-09, Effective: 10-01-09, Implementation: 10-05-09)

Routine Costs Submitted by Practitioners/Suppliers

Claims with dates of service before January 1, 2008:

- HCPCS modifier 'QV'
- Diagnosis code V70.7 (Examination of participant in clinical trial) reported as the secondary diagnosis

Claims with dates of service on or after January 1, 2008:

- HCPCS modifier 'Q1' (numeral 1 instead of the letter i)
- Diagnosis code V70.7 (Examination of participant in clinical trial) reported as the secondary diagnosis

If the QV or Q1 modifier is billed and diagnosis code V70.7 is submitted by practitioners as a secondary rather than the primary diagnosis, do not consider the service as having been furnished to a diagnostic trial volunteer. Instead, process the service as a therapeutic clinical trial service.

Effective for claims processed 90 days after issuance of CR 6431 with dates of service on or after January 1, 2008, claims submitted with either the modifier QV or the modifier Q1 shall be returned as unprocessable if the diagnosis code V70.7 is not submitted on the claim.

Contractors shall return the following messages:

Claims adjustment Reason Code 16 – Claim/service lacks information which is needed for adjudication. As least one Remark Code must be provided (may be comprised of either the Remittance Advice Code or NCPDP Reject Reason Code.)

Remittance Advice Remark Code: M76, Missing/incomplete/invalid diagnosis or condition.

Effective for claim processed 90 days after issuance of CR 6431 with dates of service on or after January 1, 2008, contractors shall disable any edits that pertain to clinical trial services being considered diagnostic versus therapeutic based on whether the diagnosis code V70.7 is submitted as the primary or secondary diagnosis.

Effective for clinical trial claims received after April 1, 2008, (regardless of the date of service) providers can begin to report an 8-digit clinical trial number. The reporting of this number is **voluntary** at this time. Refer to change request (CR) 5790 for more

information regarding the 8-digit number. Below are the claim locators that providers should use to bill the 8-digit number:

- CMS-1500 paper form-place in Field 19 (preceded by 'CT')
- 837 P—Loop 2300, REF02, REF01-P4 (do not use 'CT' on the electronic claim).

Routine Costs Submitted by Institutional Providers

All Institutional Clinical Trial Claims

Effective for clinical trial claims received after April 1, 2008, (regardless of the date of service) providers can begin to report an 8-digit clinical trial number. The reporting of this number is **voluntary** at this time. Refer to CR 5790 for more information regarding the 8-digit number. To bill the 8-digit clinical trial number, institutional providers shall code value code 'D4'---where the value code amount equals the 8-digit clinical trial number. Below are the claim locators in which to bill the 8-digit number:

- CMS-1450—Form Locator 39-41
- 837I-Loop 2300 HI – VALUE INFORMATION segment (qualifier BE)

NOTE: The QV/Q1 modifier is line item specific and must be used to identify items and services that constitute medically necessary routine patient care or treatment of complications arising from a Medicare beneficiary's participation in a Medicare-covered clinical trial. Items and services that are provided solely to satisfy data collection and analysis needs and that are not used in the clinical management of the patient are not covered and may not be billed using the QV/Q1 modifier. Items and services that are not covered by Medicare by virtue of a statutory exclusion or lack of a benefit category also may not be billed using the QV/Q1 modifier. When billed in conjunction with the V70.7 diagnosis code, the QV/Q1 modifier will serve as the provider's attestation that the service meets the Medicare coverage criteria (i.e., was furnished to a beneficiary who is participating in a Medicare qualifying clinical trial and represents routine patient care, including complications associated with qualifying trial participation).

Inpatient Clinical Trial Claims

Institutional providers billing clinical trial service(s) must report a secondary diagnosis code V70.7 and a condition code 30 regardless of whether all services are related to the clinical trial or not.

NOTE: HCPCS codes are not reported on inpatient claims. Therefore, the HCPCS modifier requirements (i.e., QV or Q1) as outlined in the outpatient clinical trial section immediately below, are not applicable to inpatient clinical trial claims.

Outpatient Clinical Trial Claims

On all outpatient clinical trial claims, providers need to do the following:

- Report condition code 30,
- Report a secondary diagnosis code of V70.7; and
- Identify all lines that contain an investigational item/service with a HCPCS modifier of:
    - QA/QR for dates of service before 1/1/08; or
    - Q0 for dates of service on or after 1/1/08.
- Identify all lines that contain a routine service with a HCPCS modifier of:
    - QV for dates of service before 1/1/08; or
    - Q1 for dates of service on or after 1/1/08.

For clinical trial billing requirements for patients enrolled in a managed care plan, please refer to Section 69.9 of this chapter.

69.9 – *Billing and* Processing Fee for Service Claims for Covered Clinical Trial Services Furnished to Managed Care Enrollees

(Rev.1723, Issued: 05-01-09, Effective: 10-01-09, Implementation: 10-05-09)

For dates of service on or after September 19, 2000, and until notified otherwise by CMS, Medicare contractors will pay for covered clinical trial services furnished to beneficiaries enrolled in managed care plans. Providers who furnish covered clinical trial services to managed care beneficiaries must be enrolled with Medicare in order to bill on a fee-for-service basis. Providers that wish to bill fee for service but have not enrolled with Medicare must contact their local carrier, intermediary, regional home health intermediary or National Supplier Clearinghouse, as appropriate, to obtain an enrollment application.

Determine payment for covered clinical trial services furnished to beneficiaries enrolled in managed care plans in accordance with applicable fee for service rules, except that beneficiaries are not responsible for the Part A or Part B deductibles (i.e., assume the Part A or Part B deductible has been met). Managed care enrollees are liable for the coinsurance amounts applicable to services paid under Medicare fee for service rules.

The clinical trial coding requirements for managed care enrollee claims are the same as those for regular Medicare fee for service claims. *However, for beneficiaries enrolled in a managed care plan, institutional providers must not bill outpatient clinical trial services and non-clinical trial services on the same claim. If covered outpatient services unrelated to the clinical trial are rendered during the same day/stay, the provider must split-bill so that ONLY the clinical trial services are contained on a single claim and billed as fee-for-service (this allows the Medicare claims processing system to not apply deductible when the patient is found to be in a managed care plan). Any outpatient services unrelated to the clinical trial should be billed to the managed care plan.*